K132304

510(k) Summary of Safety and Effectiveness

EPIQ Diagnostic Ultrasound System

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

1. **Submitter's name, address, telephone number, contact person.**

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AUG 2 1 2013

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Date prepared: June *27th*, 2013

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/usual name: Diagnostic ultrasound system and transducers
Proprietary name: EPIQ Ultrasound System

These devices are classified as follows:

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

As stated in 21 CFR, parts 892.1550, 892.1560, 892.1570, and 892.1750 each of these generic types of devices have been classified as Class II.

3. **Substantially Equivalent Devices**

Philips Ultrasound believes the EPIQ Ultrasound System is substantially equivalent to the following currently marketed devices:

Product	510(k)
Philips iU22 Diagnostic Ultrasound System	K130499, K121498, K093563, K042540, K030455

4. Device Description

The EPIQ Diagnostic Ultrasound System is a general purpose, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation.

The device consists of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics and optional peripherals (ECG, printers). In addition to the physical knobs and buttons of the main control panel, the user interface consists of a touch screen with soft key controls, and a QWERTY keyboard.

The removable transducers are connected to the system using a standard technology, multi-pin connectors. The EPIQ system uses standard transducer technology, and supports phased, linear, curved linear array, TEE, motorized 3D curved linear arrays as well as non-imaging (pencil) probes.

Clinical data storage consists of a local repository as well as off-line image storage via the network, DVR, DVD, and USB storage devices. The images are stored in industry-standard formats (Ex: JPEG, AVI, DICOM) and are intended to be readable using industry-standard hardware and software. On-line review of the images is available. Secure access tools are provided to restrict and log access to the clinical data repository according to HIPAA.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The Doppler functions of the system process the Doppler shift frequencies from the echoes of moving targets such as blood to detect and graphically display the Doppler shifts of these tissues as flow.

The EPIQ system gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used by competent healthcare professionals to make a diagnosis. The EPIQ system enables image guided navigation and image fusion via the optional PercuNav feature

5. Technological Comparison to Predicate Devices

The EPIQ system is based on the latest technology in circuitry, memory, and essential hardware. While this hardware is new, the intended use and indications for use of the device remain unchanged from the Predicate iU22 system (K130499, K121498, K093563, K042540, K030455).

Both the EPIQ system and the predicate iU22 use both hard and soft keys for operating controls. On the EPIQ system hard keys (knobs, buttons) have been changed to soft keys.

The EPIQ system offers a suite of transducers which have essentialy the same hardware save the connector. The EPIQ system has a new multipin connector which is compact as in comparison to the iU22 transducer connectors. The transducers represent the only patient contact materials of the Ultrasound System. The EPIQ system introduces no new patient contact materials that have not been previously cleared on the predicate iU22 system.

The EPIQ system is a Track 3 system that employs the same fundamental scientific technology as the predicate iU22 system.

6. Indications for Use

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetabl/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal.

The clinical environments where the EPIQ Diagnostic Ultrasound System can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

7. Safety Considerations

As a track 3 ultrasound device the EPIQ Ultrasound System is designed to comply with the acoustic output display requirements of IEC 60601-2-37 Ed 2.0 (Particular requirements for the basic safety and essential performance of ultrasonic medical and monitoring equipment) and IEC 62359, Ed 2.0 (Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields).

The EPIQ Ultrasound System complies with the referenced standard as well as the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

The system acoustic output limits are:

- Ispta.3 ≤ 720 MW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

The system and transducers are compliant to:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability, 2010
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2010

8. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the EPIQ device:

- Software Verification and Validation
- Non-Clinical Performance Data
- Non-Clinical Tests
  - IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
  - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
  - IEC 60601-1-6 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability, 2010
  - IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
  - ISO 10993: Biological evaluation of medical devices.
- Quality assurance measures applied to the system design and development include, but were not limited to:
  - Risk Analysis
  - Product Specifications
  - Design Reviews
  - Verification and Validation

9. Clinical Data

A clinical trial was not required to demonstrate safety and effectiveness of the EPIQ Diagnostic Ultrasound System. Clinical validation is unnecessary as EPIQ introduces no new indications for use, no new modes or features that have not been previously cleared on the identified predicates. The clinical safety and effectiveness of ultrasound systems with these characteristics are historically accepted for both predicate and subject devices.

10. Conclusion

The EPIQ Ultrasound System and transducers is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The predicate devices and EPIQ are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate devices and EPIQ have the same gray-scale and Doppler capabilities.
- The predicate devices and EPIQ use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate devices and EPIQ have acoustic output levels within the Track 3 FDA limits.
- The predicate devices and EPIQ are manufactured under equivalent quality systems.
- The predicate devices and EPIQ are manufactured of materials with equivalent bio safety. The materials have been evaluated and found to be safe for this application.
- The predicate devices and EPIQ are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Sites

Not applicable. No components supplied sterile.

Track

This is a Track 3 system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2013

PHILIPS ULTRASOUND, INC.
C/O MARK JOB
REVIEWER
REGULATORY TECHNOLOGY SERVICES LLC
1394 25TH STREET NW
BUFFALO MN 55313

Re: K132304
Trade/Device Name: EPIQ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 23, 2013
Received: July 29, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Philips EPIQ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-1	C8-5	C9-2
C10-3v	C10-4ec	D2cwc
D2tcd	D5cwc	L12-3
L12-5 50	L15-7io	L18-5
S5-1	S7-3t	S8-3
S12-4	V6-2	X5-1
X6-1	X7-2t	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132304

Device Name: Philips EPIQ Diagnostic Ultrasound System

Indications for Use:

Fetal/Obstetric
Gynecological
Intra-operative (Vascular, Cardiac)
Abdominal
Pediatric
Small Organ (Breast, Thyroid, Testicle)
Cephalic (Adult, Neonatal)
Trans-rectal
Trans-vaginal
Musculoskeletal (Conventional and Superficial)
Urology
Cardiac (Adult, Pediatric, Fetal, Trans-esophageal)
Fetal Echo
Peripheral Vessel
Vascular (Cerebral)

The clinical environments where the EPIQ Diagnostic Ultrasound System can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132304

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,15,16,17
	Intra-operative (Cardiac)	N	N	N	N	N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13,17
	Adult Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13,17
	Trans-rectal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Trans-vaginal	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17
	Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral vascular	N	N	N	N	N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: **C5-1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*Includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8, 9,10,11,12,13,16,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8, 910,11,12,13, 17
	Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,,8, 9,10,11,12,13, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: **C8-5**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: **C9-2**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13, 17
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Cerebral Vascular							

N= new indication

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: **C10-3v**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13, 15, 17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15, 17
	Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: C10-4ec
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note: 1,2,3	Note: 5,6,7, 8,9,10,11,12,13,17
	Trans-vaginal	N	N	N		N	Note: 1,2,3	Note: 5,6,7, 8,9,10,11,12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17
	Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,12,13
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: D2cwc
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: D2tcd
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic			N				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular			N				

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: D5cwc
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel				N			
	Cerebral Vascular				N			

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: L12-3
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: L12-5 50
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13, 17
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: L15-7io
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,8,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,12,13
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,12,13
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: L18-5
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: S5-1
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3,	Note: 6,8,9,10,12,13, 17
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13, 17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13, 17
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14, 17
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14, 17
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,13,14
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13, 17
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: S7-3t
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: S8-3
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 7,8,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: ,7,8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: S12-4
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: V6-2
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,9,10,11,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: X5-1
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: X6-1
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: ,6,8,9,10,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: ,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	N	N	N		N	Note: 1,2,3	Note: ,6,8,9,10,11,12,13
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ Ultrasound System**
Transducer: X7-2t
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav